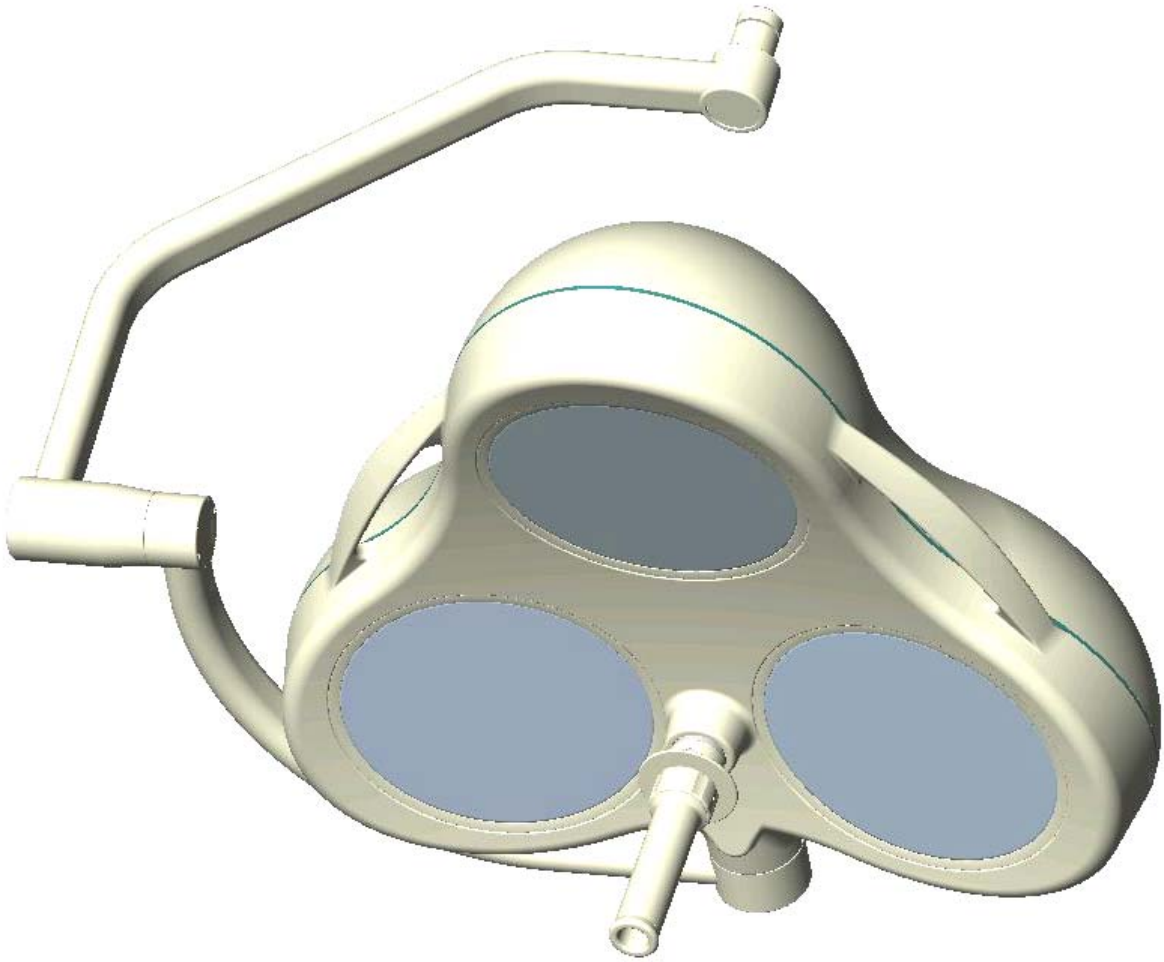
Operating instructions

MACH M3



Mach M3 stand lamp, F- / F/H / DF- / DF/H-model
Mach M3 emergency stand lamp, F- / F/H /DF- / DF/H-model
Mach M3, wall lamp, F- / F/H / DF- / DF/H-model
Mach M3 ceiling lamp for room heights up to 2,8m, F- / F/H / DF- / DF/H-model
Mach M3 ceiling lamp for room heights between 2,8m – 3m, F- / F/H / DF- / DF/H-model

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Dear customer!

Congratulations for achieving our new OT-lamp **MACH M3**.

The **MachVISION** optical system provides an illuminated field with improved contrast and excellent homogeneity. Combined with the **Duo-Focus** feature this offers a unique possibility for adaptation to the wound area.

With this lighting system you profit from a whole range of new developments, based on 50 years of experience in the production of operating and doctor's lights.

The lighting system is characterised by a previously inconceivable general colour rendition value of Ra = 96. In other words, the colours are **reproduced naturally** and in **high contrast**. The wound area is shown in a **comfortable** light.

The different reds of a wound area can now be recognised very precisely. For the doctor or surgeon this means a considerable improvement in the recognition of **details** in the **wound area**.

The R96 lighting system uses computer-optimised cold-light filters that reduce both the **unwanted build-up of heat in the head area and the heat radiated on the illuminated wound area to a minimum**.

Pay attention to the special mounting instructions for ceiling and wall lamps.

All information quoted here relates only to the illuminants. Details of ceiling or wall installation can be found in the mounting instructions.

1. Safety instructions

Pay attention to the instructions for use when handling the lamp.

WARNING:

This device has not been designed for use in potentially explosive areas.
According to the Medical Device Regulation the lamp is classified under class I.

Store the OT-lamp in its package for at least 24 hours in the respective room before mounting, in order to equal temperature differences.

Please read the instructions for use carefully to make the most of your lighting system and to avoid any damages to the device.

The lamps may only be repaired and special assembly work may only be carried out on the reflector or sockets by ourselves or a company that has been expressly authorised by us.

The manufacturer can only be made responsible for the safety of the lamp if repairs and alterations are carried out by the manufacturer himself or a company that guarantees to observe the safety regulations.

The manufacturer cannot be made liable for personal or material damages if the lamp is operated inexpediently or incorrectly or used for purposes other than those for which it is intended.

The lamp is to be dismantled from the spring arm in reverse order to its assembly. This may only be carried out after the assembly-locking device has been inserted and secured since the arm is under spring tension.

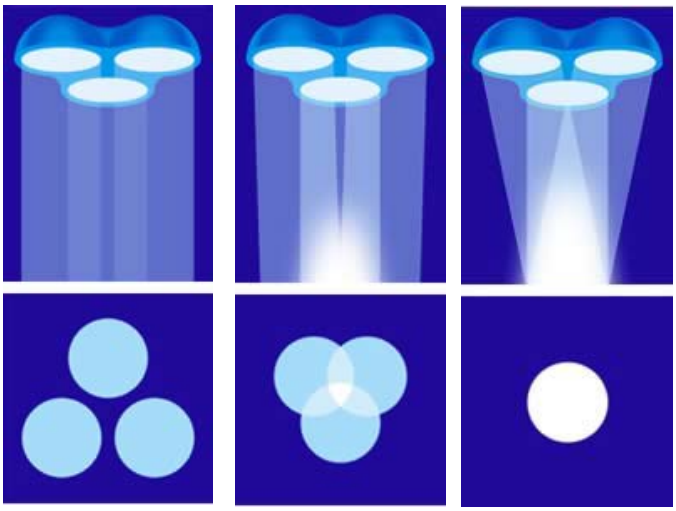
Make sure that the lamp is in perfect working order before every use.

Attention, external transformer!
The lamp works only with an external transformer 300VA.
The external transformer (Order No. 6701 0208) must be tested and validated according to IEC 60601-1.
If the external transformer is not tested and validated according to IEC 60601-1, it is not allowed to use it with Dr. Mach OT-lamps.

2. Operating the lamp MACH M3

2.1 Brief description of the lamp

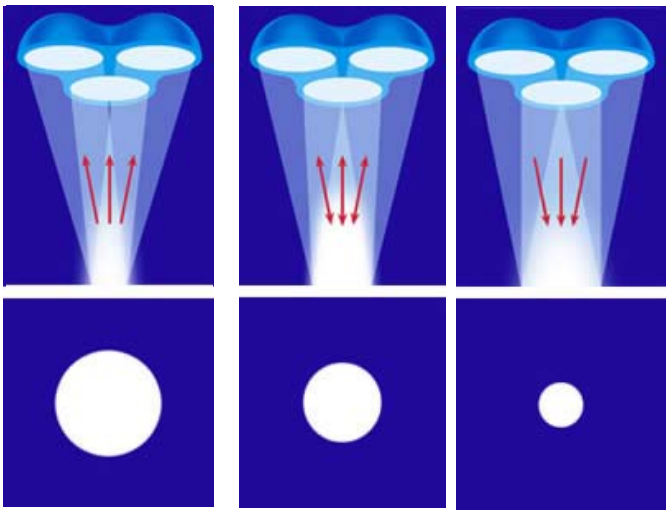
The OT-lamp MACH M3 is available in following versions:
- Standard OT-lamp (F) with merging of light fields
- Duo-Focus OT-lamp (DF) with merging of light fields and focusing
- F- or DF- lamps with light intensity control (/H)



2.1.1 Merging of light fields (F- model)

The **F-model** offers light field adjustment by **merging the individual light fields** of each reflector by swivelling them.

NOTE: This feature is activated by turning the sterilisable handle.



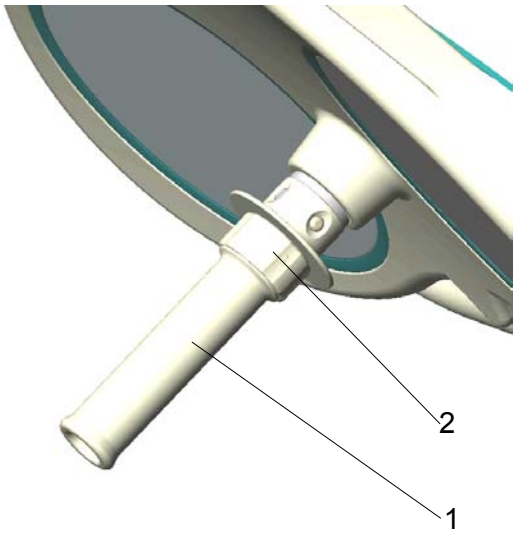
2.1.2 Focusing (DF- model)

The **DF-model** offers a second **additional** facility to further adjust the illuminated field to an extra small or extra large size, depending on the specific requirements, by **focusing through moving the bulbs up or down**.

NOTE: This feature is activated by turning the ring at the top of the sterilisable handle.

2.1.3 Light intensity control (/H- model)

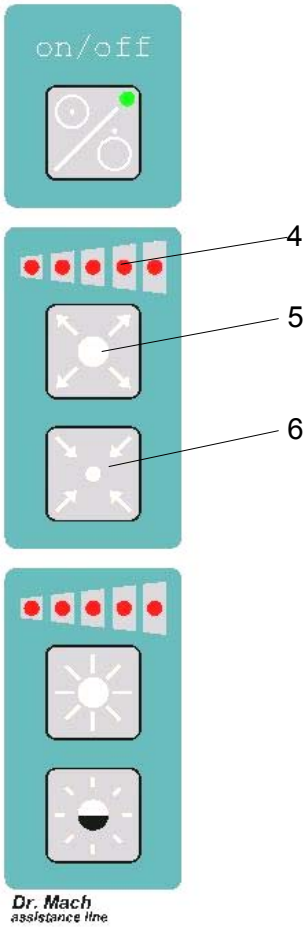
The OT-lamp models offer an optional feature, the light intensity control.
You can adjust the light intensity between 50% and 100%, according to your requirements.



2.2 Adjusting the illuminated area by merging the light fields (for F and F/H-models)

All F and F/H lamp models offer the feature of "merging the light fields". This feature is activated by turning the sterilisable handle **1**.

Remark:
The ring 2 has no function here.



2.3 Adjusting the illuminated area by merging the light fields and focusing – Duo-Focus system (for DF and DF/H models)

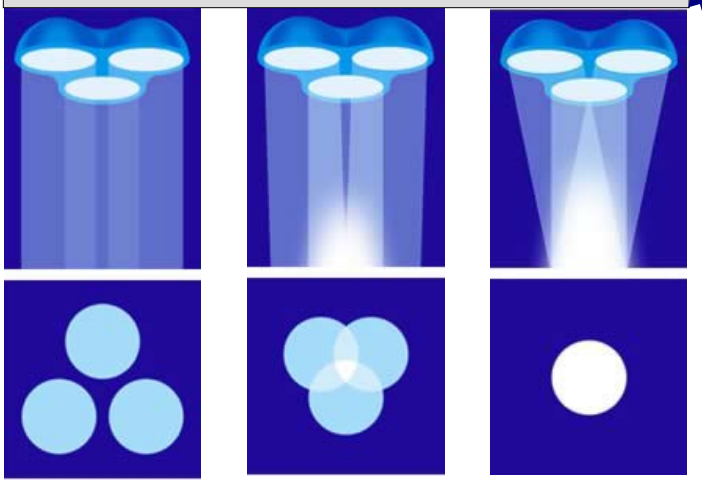
DF- and DF/H-models also have a "**focusing**" function (Duo-Focus).
The combination of merging of light fields and focusing (**Duo-Focus-system**) enables the ideal adjustment of the light field to the wound area in a range from 8 cm to 35 cm diameter. Such a large range of adjustment is not possible with conventional technique.

To activate the focusing function turn the adjusting ring **2** on the handle or, -if the lamp is equipped with a keypad at the cardan bow (for DF/H-models) – press touch buttons **5,6**.

Press touch button **5** to expand the focus and touch button **6** to bundle the light on a minimum area. The current focused diameter is shown in the LED-display **4**.

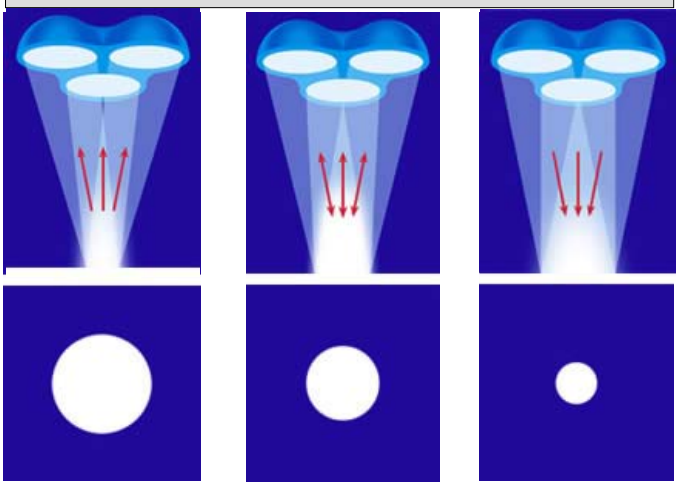
2.4 Overview of the lamp functions
Merging of light fields and focusing

MERGING OF LIGHT FIELDS

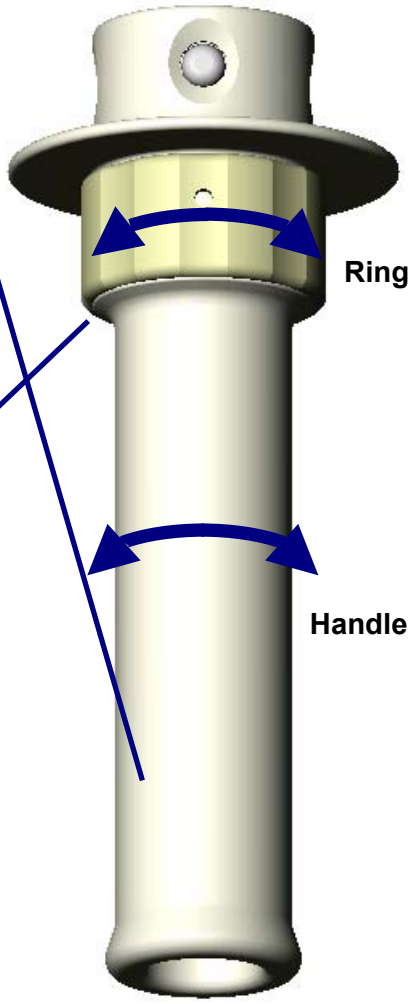


Merging the individual light fields of each reflector is done by swivelling the reflectors. The light fields overlap.
This feature is activated by **turning the sterilisable handle (1)**.

FOCUSING

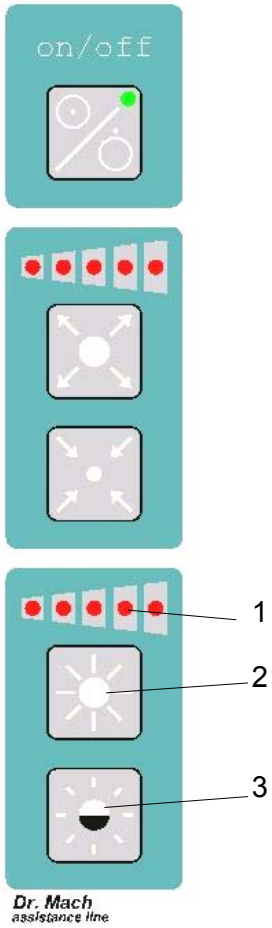


Focusing is done by moving the bulbs inside the reflectors up or down. In this way you can further adjust the illuminated field to an extra small or extra large size, depending on the specific requirements.
This feature is activated by **turning the ring (2) at the top of the sterilisable handle**.



*Always activate **merging of light fields** first by turning the handle (1), then activate **focusing** when necessary by turning the ring (2)*

Key pad



2.5 Adjusting the light intensity (for F/H and DF/H models only)

Select the desired light intensity before the operation.

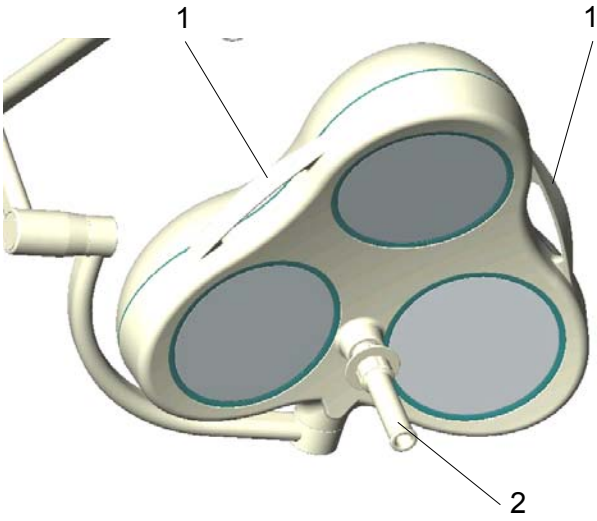
At these models the adjustment is done by the keypad at the cardan bow. The intensity can be infinitely adjusted between 50% and 100%.

Press push button **2** to increase the light intensity and press push button **3** to reduce the light intensity.

The light intensity set is shown by LED-display **1**.

For other light models we recommend a dimmer in the supply line.

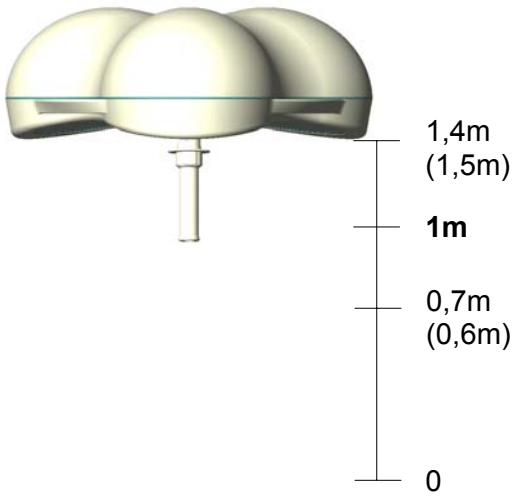
2.6 Positioning



Use the sterile handle **2** or the handle rails **1** to position the lamps.

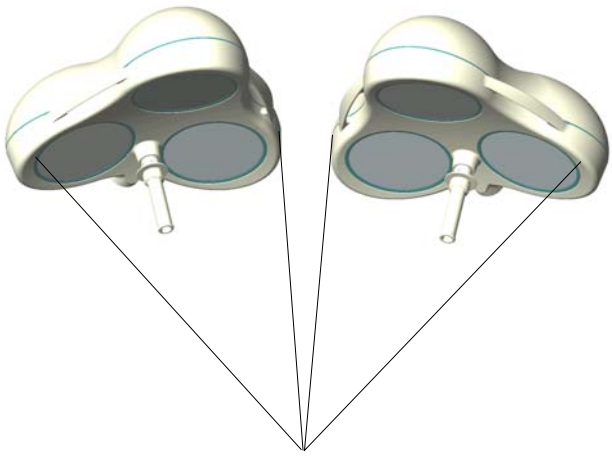
Use the handle rail to position the lights before the operation.

Use the sterile handle for positioning during the operation. This handle can be removed for sterilization.



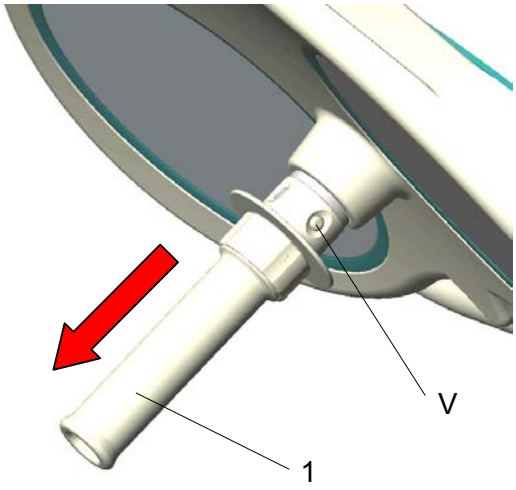
The working distance of the F-lamps is 0,7m to 1,4m.
The working distance of the DF-lamps is 0,6m to 1,5m.

The handle is supplied with a detectable mechanical catching. When the handle catches in this position, the lamp is optimally set for a working distance of 1 meter.



Two or more lamps can be used for an intensive illumination of large operation fields.
It is also possible to illuminate two operation fields simultaneously.

3. Cleaning



3.1 Sterilisable handle

At delivery the lamp is equipped with the **handle sleeve 1**. The handle sleeve is removable and sterilisable. Before using the first time and before every use the handle sleeve must be cleaned, disinfected and sterilised.

The handle sleeve must be removed for sterilisation:

- To remove press the **lock V** and pull off the sterilisable handle sleeve **1** while keeping the lock pressed.
- To attach, push on and slightly twist the handle until the **lock V** engages securely.

Handles often become unsterile during an OP; therefore always keep additional handles available for exchange.

Cleaning / disinfection and sterilisation

Basics
Efficient cleaning / disinfection is an essential requirement for effective sterilisation of the handle.
Within the scope of responsibility for the sterility of the products it should be noted that only sufficiently validated equipment and product specific processes are used for cleaning / disinfection and that the validated parameters are complied with in every cycle.
In addition, the hospital / clinic hygiene regulations must be observed.

Cleaning / disinfection
Cleaning and disinfection must be carried out immediately after use.
A mechanised process (disinfector) should be used for cleaning / disinfection. The efficiency of the process used must be recognised and validated in principle (e.g. listed under disinfectants and disinfection procedures tested and recognised by Robert-Koch-Institute / DGHM).
When using other procedures (e.g. a manual procedure), proof and process efficiency in principle must be provided within the scope of validation.
Proof in principle of the suitability of the handles for efficient cleaning / disinfection was provided using a cyclic cleaning system (Netsch-Bellmed T-600-IUDT/AN, programme 2 for small parts; code B).

It is not allowed to use agents / disinfectants, which contain the following substances, as these may cause changes in the material:

- High-concentration organic and inorganic acids
- Chlorinated hydrocarbons
- 2-ethoxyethanol

When cleaning / disinfecting, the following procedures must be followed:

	Process	**Time (sec.)**
Zone 1	Pre-rinse, external, cold, 10 – 15°C Washing, acidic, external 35°C Draining time Re-rinse, external approx. 80°C Draining time Re-rinse, external approx. 80°C Draining time	45 120 10 *10 *15 *15 15
Zone 2	Washing, alkaline, external, 93°C Draining time Re-rinse, external, acidic, 90°C Draining time Re-rinse, external 90°C Draining time	135 10 10 15 15 15
Zone 3	Drying, external 100 – 120°C	200
Zone 4	Drying, external 100 – 120°C	200
	Door open / close & transport (sluice discharge)	60
	Cycle time overall ca.	290 ≈ 5 minutes

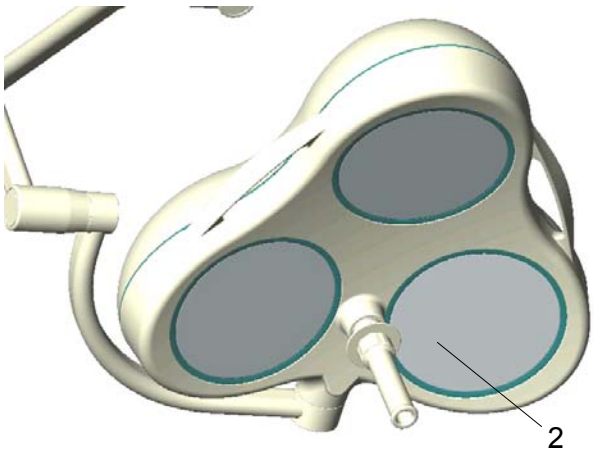
* When occupying the disinfection zone (washing zone 2), the re-rinse and draining times will depend on the respective objects being washed therein!

Sterilisation
Only previously cleaned and disinfected handles may be sterilised.
The handles are placed in a suitable sterilisation pack (one-way sterilisation pack, e.g. foil / paper sterilisation bags, single or double pack) in accordance with DIN EN 868 / ISO 11607 for steam sterilisation and then sterilised.
Use only the sterilisation procedure listed below for sterilisation. Other sterilisation procedures (e.g. ethylene oxide, formaldehyde and low-temperature plasma sterilisation) are not permissible.

Steam sterilisation procedure
Validated in accordance with DIN EN 554/ISO 11134
Maximum sterilisation temperature 134°C

Proof in principle of the handles' suitability for effective sterilisation was provided using a fractional vacuum process (Euroselectomat 666 by MMM Münchner Medizin Mechanik GmbH, sterilising temperature 134°C, holding time 7 min.)

Inspection / durability
The handles should be inspected for damage and changed before re-use, if required.
The handles may be cleaned / disinfected, sterilised and re-used for a maximum of 1000 times. If the handles are re-used more than 1000 times, then this will be the responsibility of the hospital / clinic.



3.2 Lamp housing, dispersing lens and support system

The OT-lamp MACH M3 has a high-quality surface, which can be cleaned with conventional cleaning agents.

The lens system **2** is made of a high-quality plastic. Pay attention to the following during cleaning:
- Never wipe over the lens system **2** with a dry cloth (always clean with a wet cloth).
- Only use disinfectants with **less than 20% alcohol**.

Alc. ≤ 20 %

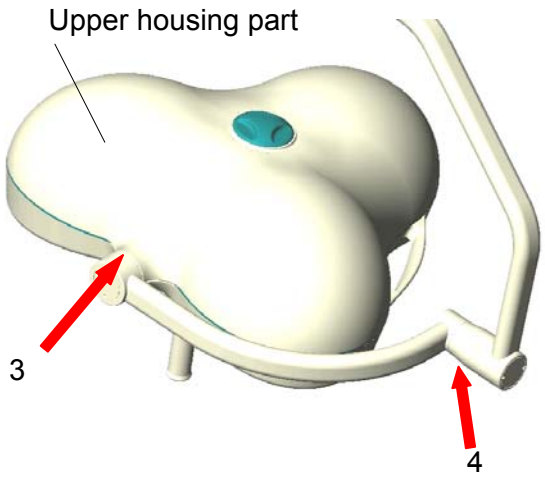
Wipe the lens system 2 after cleaning with an antistatic, non-fluffy cloth.

4. Maintenance

MACH lamps are supplied with brakes on the suspension fixture and on the lamp housing. Adjust these brakes as necessary after installation.
If the lamp is difficult to move or if it does not stay in position, the brake forces should be adjusted.

The lamps and suspension fixtures have been designed and built, so that regular maintenance intervals are not necessary.
In order to keep the system easy running throughout its life span, we recommend that the hinges should be greased once a year with acid-free grease.

When adjusting the brakes or the hinges at the ceiling attachment please consult the mounting instructions "**Ceiling attachment with heavy central axis**" or "**Ceiling / wall attachment**".

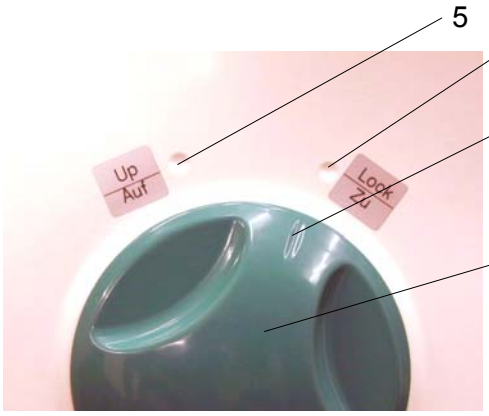


4.1 Adjustments at the lamp head

The fine adjustment for handling the lamps can be carried out at points **2** and **3**.
To adjust the brakes use a screw driver with appropriate size.

If you cannot adjust the brakes at points **2** and **3** anymore as tight as necessary, you will have to replace them.

Remark:
In order to adjust brake 2, the upper housing part must be removed.

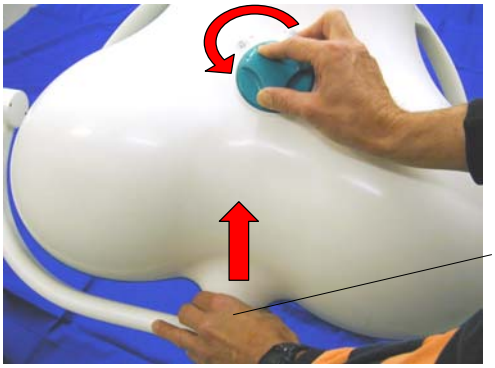


4.2 Removing the upper housing part

The upper housing part can be removed by turning the turn-lock fastener **8**.

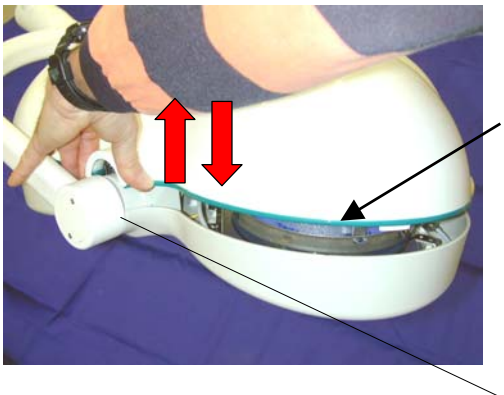
The upper housing part has two markings, **6 (Lock**) and **5 (Up)**. The notch **7** at the turn-lock fastener **8** shows the open or close status of the upper housing part.

Turn the turn-lock fastener **8** to the left over the marking **5** until stop and hold it in this position.



Lift the upper housing part with the other hand at the cardanic suspension **9** and remove it uniformly.

Be careful when removing the upper housing part, do not damage the sealing profile 10!



Mount the upper housing part in reverse order:

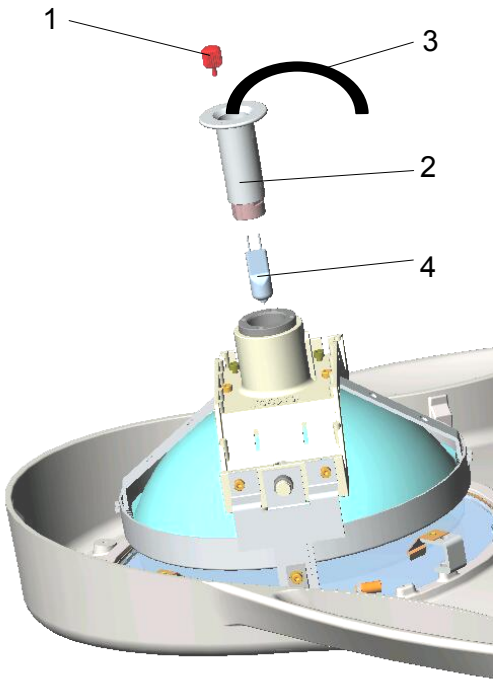
Turn the turn-lock fastener **8** again to the left over the marking **5** until stop and hold it in this position.
Put the upper housing part flush on the bottom housing part.
Be careful when mounting the upper housing part, do not damage the sealing profile 10!

Turn the turn-lock fastener **8** under slight pressure on the upper housing part to the right until the marking **6 (Lock)**.
Check by eye-control, if the upper housing part is mounted uniformly on the bottom housing part of the lamp.

4.3 Changing of spare parts

4.3.1 Changing the halogen bulbs

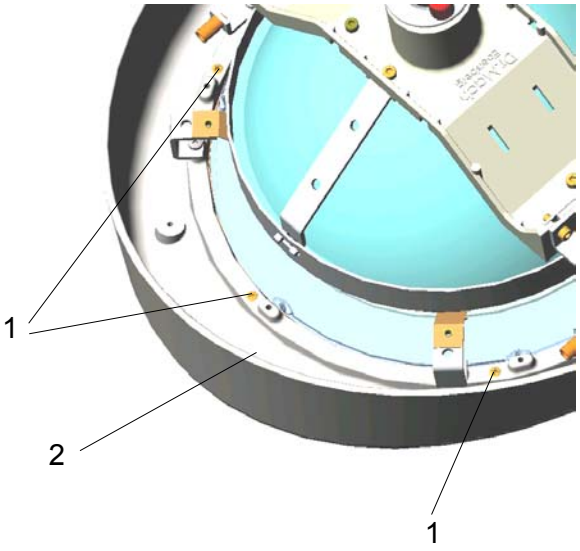
Dr. Mach uses special halogen bulbs as illuminants.
Only original Dr. Mach replacement bulbs may be used.
The use of other bulbs can lead to a considerable reduction of the light power and increase in the thermal load.
The halogen bulbs have a service life of approx. 1200 hours. We recommend changing all halogen bulbs in a lamp at the same time to keep maintenance work to a minimum.

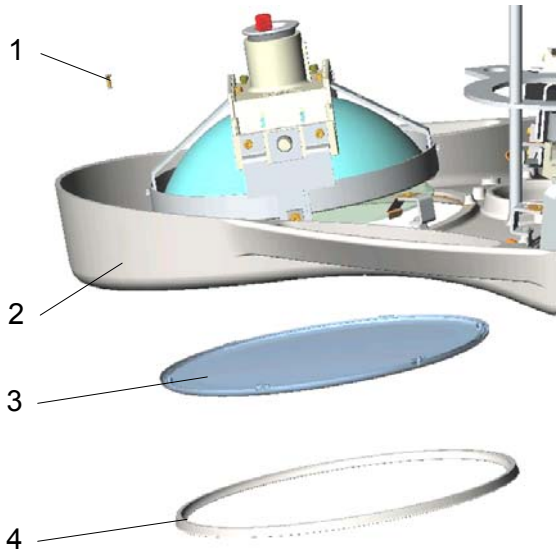


- **Turn off the lamp.**
- Remove the upper housing part of the lamp as described in chapter 4.2.
  ATTENTION: Parts of the housing and the halogen bulb may be very hot immediately after use.

- Loosen the red knurled screw **1** and remove the lamp socket **2** without removing the electrical connection **3**.
- Remove the faulty halogen bulb **4** from the socket.
  ATTENTION: Never touch new halogen bulbs with your fingers. Always use the original packaging or a clean cloth.

- Carefully insert the new halogen bulb (22.8V/50W).
- Re-assemble the lamp in reverse order





4.3.2 Changing the dispersing lens

The dispersing lens is made of a high-quality plastic. In case the dispersing lens looses its optical characteristics, this can reduce the luminous intensity and the light quality, which can be provided. It may be necessary to exchange the dispersing lens.

To change the dispersion lens proceed as follows:
Always place the dispersing lens on a soft, non-scratching base to preserve its surface.

- **Turn off the lamp.**
- Remove the upper housing part of the lamp as described in chapter 4.2.
  ATTENTION: Parts of the housing may be very hot immediately after use.

- Loosen the six screws **1** at the bottom housing part **2** with a cross screw driver.
  ATTENTION: Hold the dispersing lens 3 and the retaining ring 4 while loosening the screws 1, so the lens and the ring cannot fall down.

- Remove the dispersing lens 3 and the retaining ring 4 downwards.
- Replace the dispersing lens.
- Fix the dispersing lens and the retaining ring at the bottom part of the lamp housing.
  ATTENTION: Secure the screws 1 against loosening with safety lake and adhesive at the screw head.

5. Data

5.1 Electrical data

	Mach M3
Power consumption	150 W to max. 162 W, depending on design
Voltage AC/DC	22,8 V
Current	6,5 A to max. 7,1 A
Frequency	50 / 60 Hz
Degree of protection	Type B
Class of protection	I.

Standards IEC 601-1

5.2 Environmental conditions

Operation

	Min.	Max.
Temperature	+10°C	+40°C
Relative atmospheric humidity	30 %	75 %
Air pressure	700 hPa	1060 hPa

Transport / storage

	Min.	Max.
Temperature	-10°C	+50°C
Relative atmospheric humidity	20 %	90 %
Air pressure	700 hPa	1060 hPa

6. CE-mark

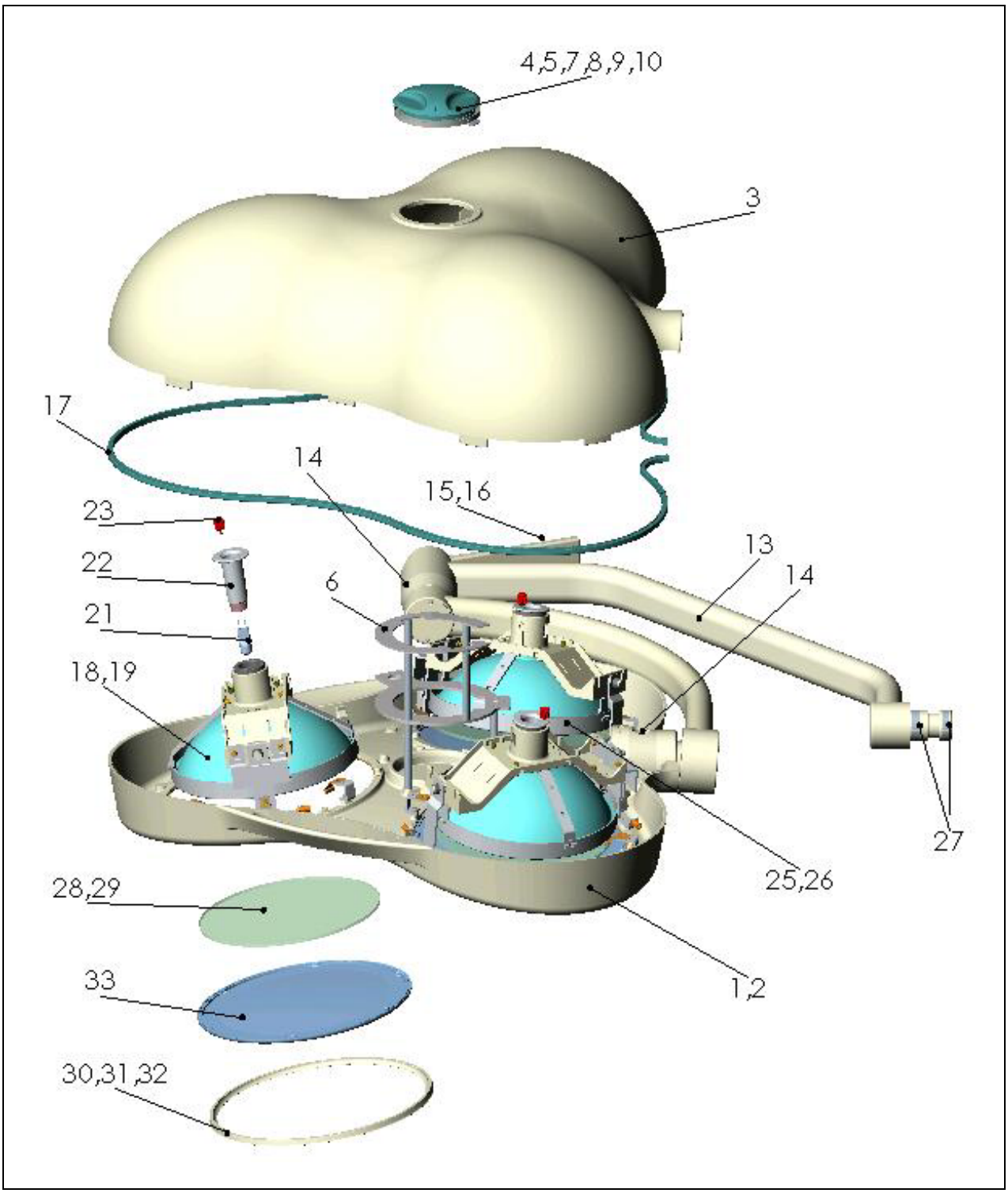
CE

The products Mach M3 comply with the standards 93/42/EEC for medical products of the European Community's Council.
Dr. Mach GmbH is certified according to DIN EN 46001:1996 and DIN EN ISO 9001:1994 by TÜV München.

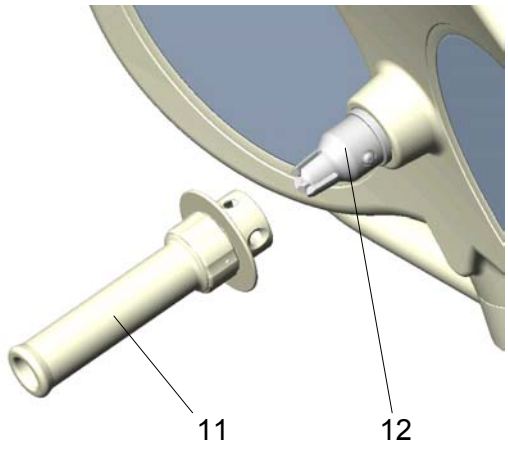
7. Disposal

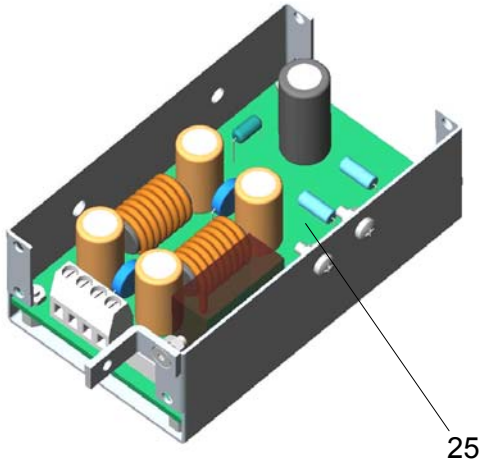
The OT-lamp doesn't contain any danger goods.
The components of the OT-lamp should be properly disposed at the end of its shelf-life.
Make sure, that the materials are carefully separated.
The electrical conducting boards should be submitted to an appropriate recycling proceeding.
The rest of the components should be disposed according to the contained materials.

8. Spare parts

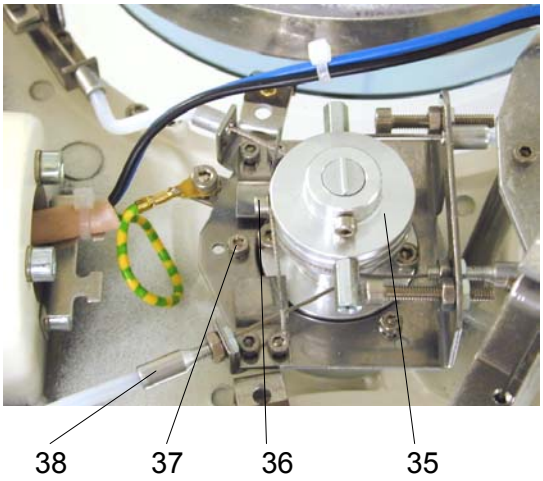


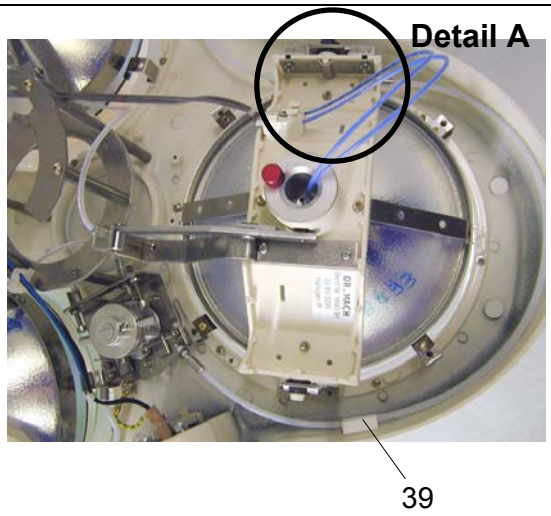
8. Spare parts - continuation



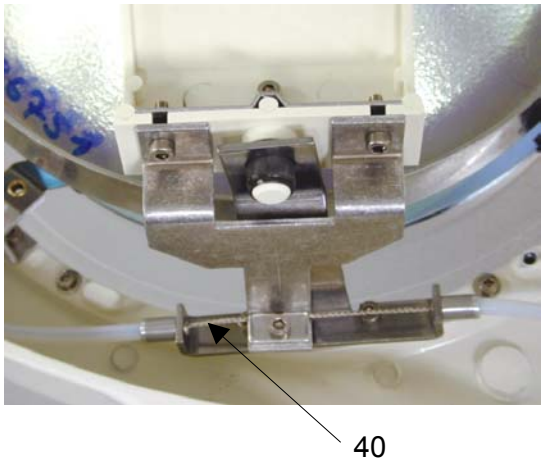


Bowden control





Detail A

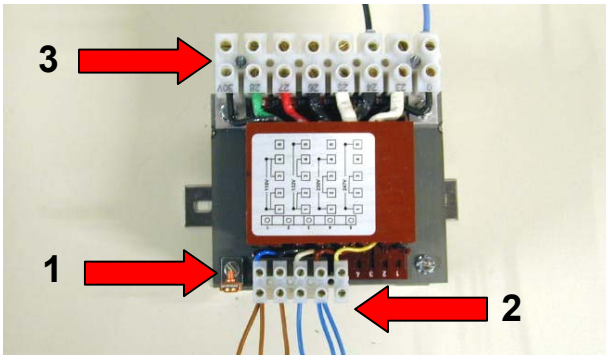


9. Spare parts list

Item	Qty.	Name	EDVNO	Remarks
1	1	Lower housing part for lamp without camera	20012204	
2	1	Lower housing part for lamp with camera	20012205	
3	1	Upper housing part	20011201	
4	1	Turn-lock fastener	20088209	
5	1	Locking washer	20088201	
6	1	Locking sheet metal	20089208	
7	1	Adjusting sheet metal 0,5	20088205	alternative
8	1	Adjusting sheet metal 1,0	20088206	alternative
9	1	Adjusting sheet metal 1,5	20088207	alternative
10	1	Adjusting sheet metal 2,0	20088208	alternative
11	1	Sterilisable handle	21150002	
12	1	Coupling DF for sterilisable handle	20220001	DF-model
	1	Coupling F for sterilisable handle	20220002	F-model
	1	Coupling DF-M for sterilisable handle	20220003	DF-M-model
13	1	Cardanic suspension		
14	1	Brake screw M12		
15	1	Keypad OPLT		DF/H-model
16	1	Keypad holder	21115003	
17	1	Sealing cord RAL 5018	20088211	
18	3	Reflector unit DF	20060001	DF-model
19	3	Reflector unit F	20060002	
20	12	Fixing screw M3x16 DIN 912 with washer	65052012	
21	3	Halogen bulb 22,8V 50W	67100201	
22	3	Socket for halogen bulb	67320007	
23	3	Knurled screw	28060213	
24	2	Fuse 0,63 AT 5x20	67370003	
25	1	Dimmer module OPDIM V3.0	24080001	Check version and number
26	1	PCB board OPDX-M3 V0.10	67250101	Check version and number
27	1	Gear motor	67030105	
28	3	Filter disk	23250201	
29	12	Spring holder	20086001	
30	3	Retaining ring		
31	18	Fixing screw M3x10 DIN 912 with lock washer	65052078	
32	18	Washer	65512017	
33	3	Dispersing lens	21200201	
34	1	Acrylic glass box for transformer 300VA	67610101	Accessory
Bowden control				
35	1	Primary shaft	20080201	
36	1	Screw M3x6:Ni ULF	65052002	
37	1	Screw M3x6 DIN 912, turned-to-size head	28082203	
38	1	Tension bolt	20080206	
39	6	Cable holder	67900006	
40	1	Round stranded rope	20080202	

10. Appendix
Setting the primary voltage at the block transformer 300VA (extra)

Clamps on the transformer



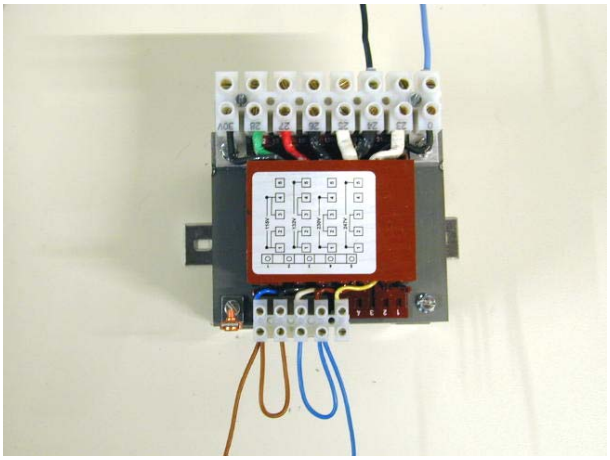
Pos.1 earthing connection at the transformer

Pos.2 primary side

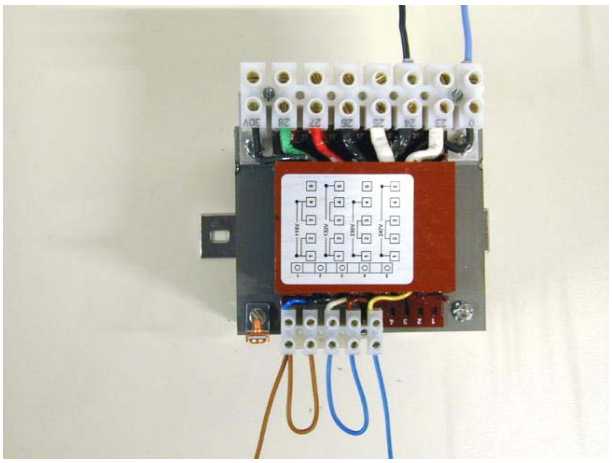
Pos.3 secondary side

- Connect the transformer to earth. Use the provided clamps **pos.1** at the transformer, respectively at the transformer plate.
  See also the explanations on page 19/46 of the mounting instructions "Ceiling and wall attachment" no. 59500001 / edition 05.

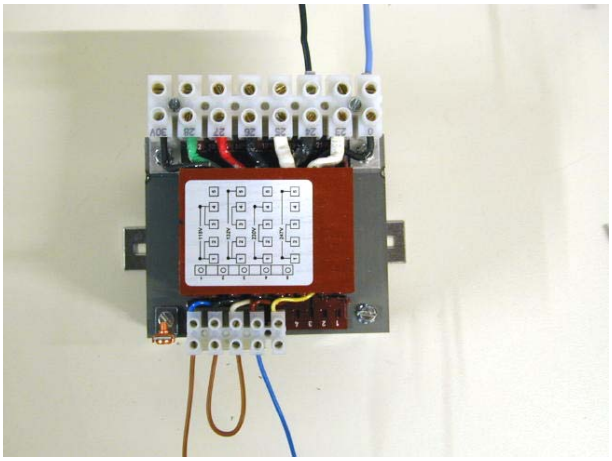
Overview of the possible settings of the primary voltage



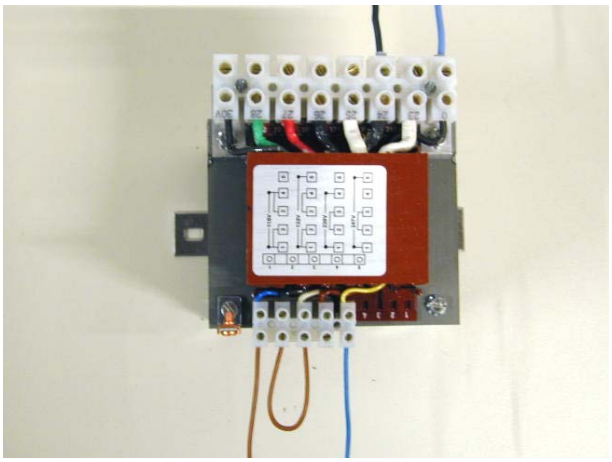
Setting for115V



Setting for 132V



Setting for 230V



Setting for 247V